CLINICAL LABORATORY BULLETIN

May 2005

Web page: http://health.utah.gov/els/labimp

❖ INTRODUCING

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NOTEWORTHY

✓ **Kudos Dr. Hammond:** M. Elizabeth Hammond, MD, was awarded the American Heart Association Distinguished Service Award for extraordinary service to the heart transplant programs in hospitals throughout Utah. Dr. Hammond is professor of pathology and adjunct professor of internal medicine at the University of Utah. She is also Office of Research Director at Intermountain Health Care (IHC).

✓ **Reduce Errors in Point of Care Testing:** James H. Nichols, PhD, DABCC, FACB discussed ways to reduce testing errors in non-traditional laboratory settings in the May, 2005 Lab Medicine issue. Dr. Nichols emphasized:

Many "lab errors" are actually caused by poor communication, actions by persons other than testing personnel, or poorly designed processes over which the lab has no control.

Training must include proper specimen collection and results interpretation – not just doing the test correctly.

For patient identification errors retraining was not as effective as sample bar coding to automate data entry.

"The use of data management systems to review and sort all of the available POCT data has been a better source for detecting our errors and further allows us to estimate the frequency of errors in our health system as a monitor for improvement."

✓ **New FDA Tissue Rule:** May 25, 2005 the FDA's rule, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products became effective. The rule requires certain communicable disease testing to be done (varies by cell or tissue type) by a CLIA certified lab and requires all testing facilities to register with the FDA.

The rule does not apply to vascularized human organs for transplantation, whole blood, blood components, or blood derivatives. For the complete regulation go to FDA's website at http://www.fda.gov/cber/rules/suitdonor.htm.

✓ **CLIA Answers Histopathology Questions:** 1. H & E is a differential stain

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which requires a control slide be stained with each patient slide or group of patient slides.

2. The laboratory must retain every slide it processes and interprets from a Mohs surgery specimen.

3. You must make certain a facility that screens your slides is CLIA certified. You do **not** need a copy of their certificate in your office.

4. There are no workload limits for reading dermatology slides.

✓ **Microscope Maintenance:** Even if you have a contract person service your microscope annually, here are a few things you can do to improve its performance between maintenance cycles by keeping it clean and dust free.

1. Remove dirt/dust with a brush, with canned air and then wipe with a soft cloth. You can remove the ocular eyepiece and turn it upside down to use as a magnifying lens to ensure you remove all dirt and dust from the other lenses.

2. Place a few drops of lens cleaner on lens paper or a cotton swab to clean the eyepieces and lenses. Never apply the liquid directly to the lens surface as it may seep around the edges into the lens.

3. Gently wipe the glass surfaces in a circular motion from the center outward.

4. Always cover your microscope when not in use – we live in the dessert!

5. Brush glass surfaces and dust the entire microscope each day of use. Weekly blow off glass slide slivers from the stage. Clean with lens cleaner as needed – and after using the oil lens. A clean microscope is a happy one.

✓ **Validating the aPTT:** John D. Olson, MD, PhD wrote an article for the October, 2004 issue of CAP Today titled "How to validate heparin sensitivity of the aPTT". He gave information on three methods: Using a heparin assay; using ex vivo heparin specimen comparisons; and instrument recalibration. "the variability in sensitivity of reagents to unfractionated heparin is not limited to any one manufacturer or lot number of a manufacturer's reagents. Failure to pay attention to this issue can lead to patients receiving too much or too little heparin, with the possible complications of bleeding or thrombosis."

Just as INR is an attempt to standardize PT testing, heparin sensitivity validation will help standardize the aPTT. If you monitor unfractionated heparin therapy you "must determine the sensitivity of the method to heparin, inform the clinicians of the sensitivity, and recommend a therapeutic interval. This must be done each time there is a change in the method."

For details on the methods Dr. Olson recommends, read the entire article in CAP Today (www.cap.org).

✓ **Measuring CO_2 Accurately:** There are published studies showing a decrease in CO_2 values during routine processing (up to 4.1 mmol/L); in open-cup instrument systems (up to 8 mmol/L); and in under-filled tubes (as much as 42% in four hours). One study demonstrated properly filled, refrigerated tubes showed very little decrease.

✓ **Positive Blood Cultures = Patient Septicemia or Contamination?:** What is your facility's blood culture contamination rate? No laboratory should have a 0% rate. If you have an adequate culture method, and perfect phlebotomists, you should see an occasional transient bacteremia (a few bacteria traveling in the blood stream picked up in your culture tube before the patient's WBCs had time to engulf them). Your contamination rate should not be over 3% according to American Society of Microbiology literature.

Studies show facilities with the lowest contamination rates have a trained phlebotomy staff collect >90% of their blood cultures. The highest contamination rates are in cultures collected from indwelling catheters or heparin locks.

One study shows iodine tincture is a more effective skin cleanser than povidone types. Using the cleanser to clean the tops of the culture bottles also cuts contamination rates. If you can't use an iodine solution, properly applied chlorhexidine scrubs work as well.

Using the proper collection equipment, correct collection techniques, and a specially trained phlebotomy staff will help lower your culture contamination number.

✓ **Testing for Ecstasy:** 3,4-methylenedioxy-methamphetamine (MDMA) is known on the street as Ecstasy. The only illegal drug more popular today is marijuana. There is no current clinical use sanctioned for this drug, but researchers are investigating its use to treat traumatic stress disorder.

MDAD will test positive in drug screen kits used for amphetamines and derivatives. While a good screening test, confirmation is needed to tell exactly which drug a patient used. There are newer, antibody specific urine screening kits available. If your patient population includes college students or large urban youth groups, you may want to add such a kit test to your drug screens.

✓ **eQC:** If you choose to follow the CLIA equivalent quality control procedures (eQC), remember the manufacturer's control requirements must be met also. If the manufacturer says you do external controls on each new box of RSV test cartridges, and you open the new box before the next regular eQC testing day, you run those external levels before you test patients. If the manufacturer instructs you in what constitutes two levels of internal control, and states those internal controls should work properly for accurate test results, you must document the internal controls perform as expected each day of testing before accepting patient results.

In addition to your routine eQC procedures, external controls must be tested with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, and following critical parts replacement that may influence test performance. If these quality control requirements coincide with your regularly scheduled eQC, there is no need to do them twice.

FROM THE PATIENT'S CHART

"The skin was moist and dry."

☆ Feature ☆

STANDARD PRECAUTIONS:
LESSONS LEARNED

"WARNING: POTENTIALLY HAZARDOUS MATERIAL" information bulletin was sent by the College of American Pathologists (CAP) to laboratories throughout the country and the world in April, 2005. The Association of Public Health Laboratories (APHL) had already contacted epidemiologists and public health laboratories in each state to assist in disseminating information and monitoring the laboratory community for possible serious influenza A infection. Why all the fuss?

A particular influenza A virus strain, H2N2, was used to prepare proficiency (PT) test samples for the first testing event of 2005. This strain had been unusually virulent and lethal in influenza outbreaks before 1968. The strain is not in the current vaccine formula as it hasn't been documented since 1968. Although no transmission from proficiency test samples to laboratory workers was reported, this is an excellent "wake-up" call.

At first, the risk was thought to be small – only labs who cultured for influenza A virus. Then the picture expanded. Three proficiency test providers were supplied with the H2N2 strain. The samples were used in antigen detection kits as well as culture kits. These samples were sent to hospital, reference, clinic and doctor's office laboratories.

The Utah Division of Epidemiology and Laboratory Services went into immediate action. Thirty-seven Utah facilities who received the samples were called. They were asked to destroy the vials (if they hadn't already) and contact the Department of Health if any employee who came in contact with the samples developed flu-like symptoms.

While no persons were reported to have been infected by the PT virus strain, each laboratory should review their policies for handling potential infectious materials. Patient samples, control materials, and proficiency test samples may contain infectious organisms. Every laboratory should follow the Center for Disease Control and Prevention's (CDC) Standard Precautions. This precaution tells us to treat **every sample** as if it contained a deadly virus. Check your policies. Do you:

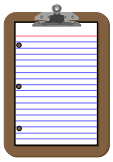
Use gloves when handling any patient, control or proficiency test sample?

Always were a properly fitting lab coat when working in the lab?

Work with high risk samples (identified by OSHA in their Bloodborne Pathogen Standard) or while performing tasks likely to cause aerosols in a Biological Safety Cabinet?

Wash your hands after removing gloves and before leaving your work area?

Let's not get into the medical journals by being a casualty statistic.



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Cardinal Health SP Rapid Test Strep A Cassette and dipstick, and H. pylori test

° Phamatech Quickscreen multi drug screen – Models 9177X and 9178X

° PSS Select Urine Analyzer

° BioSys Laboratories UriScan Optima II Urine Analyzer

° Accumetrics VerifyNow-Aspirin Assay

° Polymer Technology Systems Cardiochek Analyzer and Bioscanner Plus

° Accu-Stat Drugs of Abuse Home Test for various analytes

° Wampole Laboratories Clearview H. pylori II and Clearview RSV

° McKesson Medi-Lab Performance Mononucleosis Test

° ACON Laboratories On Call Multi-Drug Home Test and One Step Multi-line Test

° Genzyme OSOM Trichomonas Rapid Test

° Akers Laboratories Inc InstaRead Lithium System

° PerMaxim RadiScreen H. pylori Test Device

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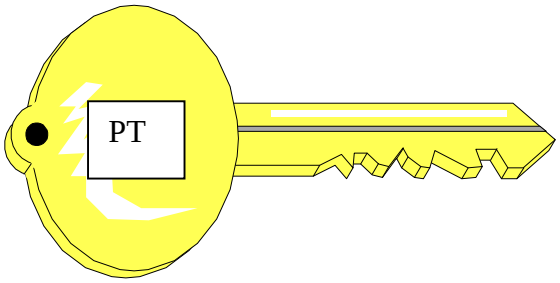
CPT Code change for 2006

Are you denied payment for occult blood tests when you send the patient home with 3 guaiac cards to collect specimens and return them to your lab? You were paid for one test, but the other two were denied? The new test description for CPT code 82270 should help clarify the issue. Code 82270 will state: "blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces; consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)". This revised description means you are checking for blood from a single office visit by collecting up to three consecutive samples. The revised explanation should clarify the code payment as it always existed (you will be paid for one test, not 3).

There will be a new code (CPT 8227x) blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces; single specimen, (e.g., from digital rectal exam)."

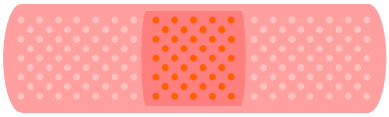
Equals

"Ratio of an igloo's circumference to its diameter: Eskimo Pi"



Cytology Proficiency Testing

CLIA reported to all regional offices and state agencies "New graduates of schools of cytotechnology who have taken and obtained a passing score on the American Society for Clinical Pathology (ASCP) Board of Registry (BOR) Certification Examination in Cytotechnology are **not** required to participate in a CMS-approved Cytology Proficiency Testing event during the calendar year they pass their ASCP BOR Examination."



SAFETY

Help slow the development of drug resistant organisms by using the most effective topical antiseptic for the purpose. Here are the FDA's 1994 product categories and definitions:

Antiseptic Drug: " it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

Broad Spectrum Activity: "containing an ingredient included in the monograph, that possesses in vitro activity against the microorganisms listed in 333.470(a)(1)(ii)."

Healthcare Antiseptic Drug Product: "An antiseptic containing drug product applied topically to the skin to help prevent infection or help prevent cross contamination."

Antiseptic Handwash Product: "An antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad spectrum, fast acting and, if possible, persistent."

Surgical Hand Scrub Drug Product: "An antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin; it is broad spectrum, fast acting, and persistent."

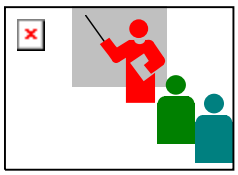
Patient Preoperative Skin Preparation Drug Product: "A fast acting, broad-spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin."

Check your product's package insert for its FDA approval classification. See if the product does what you need it to. Always follow the use instructions exactly. If you use the wrong product or use it incorrectly, organisms may survive and become resistant to the antiseptic. You can spread these resistant organisms to patients or family members. Immunocompromised persons are much more susceptible to infection and resistant "normal flora" organisms can give them serious disease.

"A new problem is as good as a vacation."

Golda Meir

CONTINUING EDUCATION



Bureau of Laboratory Improvement (BLI)

The National Laboratory Training Network (NLTN) is offering to bring CDC parasitology wet workshops to Utah. Courses available in 2006 include: Intermediate Parasitology (2 days); Malaria & Babesia (2 days); and Intestinal Parasites with emphasis on cyclosporin and cryptosporidium (1 day). The cost is $75 for 1 day and $150 for 2 day courses with a minimum of 20 participants. If you are interested, please contact Rebecca Christiansen at rchristiansen@utah.gov or phone 801-584-8471.

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Book

The *Phlebotomy Workbook* by Susan Strasinger and Marjorie DeLorenzo is available on Amazon.com for $35.95 in soft cover. The 424 page book (ISBN 0803610491; Philadelphia: F.A. Davis Company, 2003) covers how to get a good specimen with less negative impact on the patient. Chapters cover safety, general lab procedures, basic anatomy, cytology, and immunology that demonstrate the need for quality patient samples. There is also information on CLIA regulations and legal liabilities. Photographs show technique and the latest available equipment to make the phlebotomist's job easier and more effective.